IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

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| UNITED STATES OF AMERICA, EX REL. MELINDA JENNE,<br><br>Relator<br>Vs.<br><br>BOSTON SCIENTIFIC<br><br>Defendant | Case No: 11-cv-1054<br><br>**FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 USC § 3730** |

**QUI TAM RELATOR'S COMPLAINT FOR DAMAGES UNDER 31 USC 3729 ET SEQ., FALSE CLAIMS ACT**

COMES NOW Relator, Melinda Jenne, by and through her counsel of record, and in support of her allegations of false claims states and avers as follows:

1. This is a qui tam cause of action brought under 31 USC § 3729, the False Claims Act, for damages and civil penalties arising from the submission of false claims to the United States. Jurisdiction is proper under 31 USC § 3730 and 28 USC § 1332.

2. Prior to the filing of this complaint the Relator has provided a detailed evidentiary disclosure to the United States Attorney for Missouri.

**VENUE**

3. The acts giving rise to this cause of action occurred, at least in part, within the state of Missouri and within this judicial district. The

corporate defendant transacted business in the Western District of Missouri by doing business with hospitals in Boone and Cole County. Venue is proper under 31 USC § 3730.

**PARTIES**

4. Relator Melinda Jenne, is a former employee of defendant Boston Scientific, Inc. She worked as an "ISS" (Interventional Sales Support) and provided clinical consultation and assistance to hospitals and physicians in the mid-Missouri market (seeing clients at hospitals in St. Louis, Boone County, Cole County, and other counties). She brings this action pursuant to the provisions of the Federal False Claims Act. Prior to filing this action she disclosed the conduct at issue to the United States voluntarily through her attorneys.

5. Defendant Boston Scientific, Inc., is a foreign corporation (Delaware) in good standing with the state of Missouri whose registered agent for service of process is CSC-Lawyers Incorporating Service, 221 Bolivar Street, Jefferson City, MO 65101

**BACKGROUND FACTS**

6. Percutaneous Coronary Intervention (PCI) is the branch of cardiology that implants stents (either drug-eluting or bare metal stents) into coronary arteries to improve blood flow in situations where blood flow

is impaired. Central to this branch of cardiology is the availability of stents. More than two million people world-wide receive stents every year.

7. Stents are used in large numbers and are high-cost items. Persons selling stents for major US manufacturers and covering a sizeable territory are compensated on commission, and frequently earn in excess of $400,000 per year. Sales representatives with the best numbers often win free trips and other additional compensation.

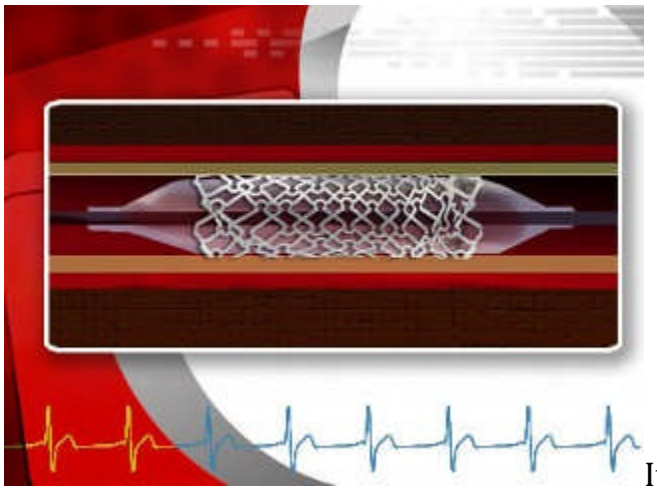
8. This complaint focuses on the unlawful behavior of Boston Scientific, Inc., a relatively large (in terms of the number of employees) medical equipment manufacturer supplying stents and other goods to hospitals in the State of Missouri.

9. A copy of an evidentiary disclosure required by 31 USC § 3730 is being served concurrently with this Complaint on the United States Attorney for the Western District of Missouri, and on the Honorable Eric Holder, Esq., in Washington DC.

10. Cardiac stents are the treatment of choice for narrowed coronary arteries that do not require open-heart surgery. When patients develop blockages in the coronary arteries, these blockages are made up of fats and lipids, cholesterol, and sometimes very hard material

such as calcium. One good analogy is to think of a blockage in the artery of the heart in terms of plumbing. When a patient's arteries get blocked, there are two ways to basically fix them. One way is by bypassing the blockage. This is surgically placing a graft before the blockage and then tying the graft back in after the blockage. The other way is actually working on the blockage inside the artery. That's what a stent does.

11. A stent is a little metallic cage inserted through a wire.



It's made out of usually surgical-grade stainless steel or other type of metallic alloys, and it pushes open and holds open the blockage from the inside out, and, therefore, it restores normal blood flow. The real advantage of a stent procedure, compared to surgery or other forms of opening up blockages, is that it is much easier for the patient. There is much less pain, the recovery is faster, and most patients go home the next day.

12. There are two types of stents. As a general classification the cardiologists choose from: bare metal stents and special, coated stents, which are called drug-eluting stents. The stents are the same as far as their metallic backbone.

13. The stents hold open the blockage. If there are any tears in the artery, they seal and fix the tears, and the result is a, wide-open blood vessel at the end of the procedure.

14. However, with a bare-metal stent, in approximately 30 percent of patients within the first six months or one year, the blockage will re-narrow. Often this is due to the normal body's way of healing an injury. Now most people, approximately two thirds, will get a thin little scar or scab inside the artery, and that heals the artery very nicely. But approximately a third of patients will have an excessive amount of scar or scab form, given the size of the artery, because these arteries are actually quite small, and that will gradually re-narrow the artery within the first six or twelve months, and that's called re-stenosis. When that happens, a patient who was initially feeling very well will suddenly get his discomfort back, his angina, or get short of breath again, or have other limitations that requires another visit, and usually either another angioplasty or, in some cases, bypass surgery.

15. A drug-eluting stent is meant to try to prevent the scar tissue from coming back, and there are several different types now that basically have a special drug that delivers the agent right at the site of the injury to the artery and prevents much of the scar tissue from recurring. The likelihood of the arteries re-narrowing after drug-eluting stents are much less than after bare metal stents, but these are very potent compounds, and sometimes they cause the artery to heal to a minimal degree.

16. Stents are placed inside the arteries using a wire that is threaded up through the femoral artery. Stents are selected based on the size of an artery, and while x-ray technology allows for some measurement of the size of the arteries involved, it is inexact. In some instances when a stent is threaded to the site where it is needed, it is simply too large to go into the narrowed artery. Doctors have a special term for this: "no cross." Essentially the stent would not cross the arterial barrier.

17. Stents are high-cost items to hospitals, averaging in the neighborhood of between $1,000 to $4,000 per stent. The competition among makers of these devices for market share is intense, and while physicians place the stents, hospitals routinely pay for them.

18. Most companies, including Boston Scientific, have commissioned sales

persons to represent their products in the marketplace. Boston Scientific identifies this position as a "CSR" (Coronary Sales Representative) and it is highly remunerated, with salaries after bonus ranging between $300,000 and $900,000 per year on information and belief.

19. Obviously once a stent is opened and placed on a wire inside a patient, if it cannot be implanted, it must be disposed of.

20. Although the error, if any, is the physician's, the stent companies normally issue credits for such "no crosses" and replace stents that are lost due to this reason.

21. Relator is a former employee of Boston Scientific, Inc., and very much enjoyed her job. She especially enjoyed the opportunity to work with physicians and the feeling that she was making a difference for patients. However, when she identified the scheme at issue in this complaint, she was forced out of the company for complaining about the unethical and illegal conduct brought forth in this complaint.

22. Relator was trained to company policy at the home office in Minnesota. Her field training was done by CSR Dave Raridon. This was unusual because ISS personnel are normally trained in the field by other ISS personnel. Management told Relator to take her questions to Dave

Raridon. Raridon bragged that he always got a distinguished rating (the highest awarded) by the company. Management supervised her very infrequently. To the best of her knowledge, information and belief, management never rode along with or accompanied Raridon on sales calls.

23. Raridon taught Relator to call in to Boston Scientific legitimate "no crosses" for hospitals Relator serviced. When Relator went to accounts by herself she could provide this service to the hospitals in furtherance of her clinical mission for the company. To her knowledge she never called in a "no cross" that was not legitimate. She did not know, at the time, that Raridon was using illegitimate "no crosses" for a different and unlawful purpose.

24. Prior to her employment Raridon and other CSRs for Boston Scientific had access to "trunk stock." Trunk stock was the generic name for extra pieces of product that the reps could carry in their car trunks and give away at facilities as an inducement to sales. Right before her employment trunk stock was discontinued. Raridon, however, found a way to obtain trunk stock.

25. Raridon would call in "no crosses" for patients and procedures that did not exist, would then pick up the stents shipped to the hospital as

replacements for the "no crosses" and use those as his own personal supply of free goods with which he would induce sales of the company's products. If he ever did inventory and the hospital had too many stents he informed Relator that he would take the "extra bullets" and use them at a later date.

26. In addition, Raridon sometimes would make deals with hospitals where they would order lower priced goods, and when those came in he would swap them out for higher priced goods, thereby providing them with an indirect and nearly untraceable kickback.

27. In one example, Relator became aware that at St. Mary's Hospital the CSR, Dave Raridon, made a deal to supply the hospital not only with stents, but with a certain free number of stents as an inducement to do a "bulk order." This bulk order affected her statistics. Relator's manager denied that Raridon had done a bulk order. Relator obtained proof from the hospital that he had done such an order, and that he had given away free goods to obtain the order.

28. Relator provided her proof and evidence to the company. The Defendant company promised an investigation. However, instead of an investigation, Relator was told that the salesperson had done nothing wrong because what he had done was "policy that month." She was

told never to bring up the subject again internally or discuss it with anyone or she would be terminated.

29. At the time of her disclosure to the company the Relator was unaware of the provisions of the Anti Kickback Statute and did not know that what Raridon was doing or had done violated federal law.

30. Thereafter the company increased the geographic area she was required to travel in, gave her additional duties, and changed the terms and conditions of her employment to such a degree that she was forced to resign.

31. An overview of the issues in the complaint is as follows:

a. Boston Scientific, Inc., had a policy that allowed salesmen to call in "no crosses" from hospitals in order to have another stent shipped to the hospital for stents that could not be used.

b. No supporting documentation was required by Boston Scientific in support of a "no cross."

c. The salesmen, and specifically Dave Raridon, who was always a number one selling stent salesman with Boston Scientific, used "no cross" stents as a form of illegal kickback to hospitals. At least 10 people in the St. Louis area used Raridon's sales tactics to Relator's

knowledge.

d. Raridon was frequently tasked with training other sales people on how to generate additional sales using "his techniques." Management encouraged him to train others.

e. While some managers may not have been aware of the specifics of Raridon's training, it was well known throughout the company that those trained by Raridon and those who followed his "extra bullets" methodology, were the ones that consistently won sales promotions, trips, and other accolades within the company.

f. On information and belief, and as a justifiable inference from the sales results, managers at Boston Scientific likely knew that Raridon was using means and methods that the company could not openly embrace, and for that reason Raridon's training was sought out by managers for new sales trainees.

g. Relator brought this to the attention of the company as set forth above, and the company not only failed to interdict the unlawful kickbacks, they threatened to fire the Relator if she discussed the issue further.

32. There are four separate classifications of Medicare[1] and Tricare fraud alleged

[1] Relator intends to include within the definition of Medicare those Medicare opt-out or Medicare HMO plans such as Humana Gold, Coventry Advantra, Secure Horizons and others. These plans,

in this complaint. These are:

i. Causing the submission of false claims by hospitals (§ 3729(a)(1)(A)) related to violations of the Anti-Kickback Statutes;

ii. Creating false records material to false claims (§ 3729(a)(1)(B)) related to violations of the Anti-Kickback Statutes;

iii. Engaging in a conspiracy with hospital purchasing agents to obtain free goods through false "no cross" credits in violation of § 3729(a)(1)(C); and

iv. Reverse False Claims § 3729(a)(1)(G) related to the failure to repay Medicare, Medicaid and Tricare for stents improperly billed in violation of the Anti-markup and Anti-Kickback provisions.

33. In addition to not requiring any paper trail or audit procedure to verify that "no crosses" actually occurred at hospitals, supervisory sales managers actually encouraged the use of "no cross" and similar "freebies" by the sales staff, even creating code words ("extra bullets") to encourage sales persons to

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although administered by commercial insurers are paid by Medicare and therefore fall into the same compliance requirements as Medicare.

give these incentives to hospitals.

34. The "extra bullets" and "no cross" kickbacks were preferred as a method of providing free goods to hospitals because of the way the "no cross" stents were handled.

    a. The rep would call in the no cross to the company.

    b. The stents would be shipped to the hospital.

    c. The reps would often pick up additional stents from the hospital and take them home so that they could be given away as free goods to other facilities.

    d. The method used essentially ensured there would be a very illusory paper trail on the stents, insured the complicity of the hospital purchasing agents, and worked to the benefit of both Boston Scientific and the Hospitals.

    e. Some hospitals may not have known they were having "no cross" stents funneled through their facility. Raridon would just tell hospital purchasing managers he was having stents sent as extras and to just set them aside. He would inventory their stock to make sure they received all they were supposed to receive, and take the extras saying that they were his.

35. Another way that Boston Scientific, Inc., encouraged the use of the kickbacks as a means of gaining market share is evident from the competitions they ran for sales persons. Sales persons with the highest overall sales were recognized with trips, bonuses, and recognition at national meetings. Yet at no time did anyone at Boston Scientific attempt to compare the correlation between the exceptionally high number of "no cross" call ins from those sales person's territories. Had they done so they would have seen that there was a direct correlation between the number of no cross stents sent to those sales persons regions that far exceeded the national average of no-cross stent placements[2]. In general, the same representatives tended to win these trips and competitions all the time.

36. The overall purpose of the kickbacks and the provision of free goods to hospitals was to ensure that competing stent manufacturers never gained a foothold at hospitals serviced by Boston Scientific.

**The False Claims Act**

37. The False Claims Act, 31 USC § 3729, provides, in pertinent part, that:

(a) Liability for certain acts.

[2] See Ellis, Auditing Implantable Medical Devices: A Synergistic Approach for Bottom Line Results, New Perspectives, Association of Healthcare Internal Auditors, 8-10 (Aug. 2008) available on line at http://www.ahia.org/audit_library/newperspectivesarchive/new_perspectives/2008/Summer2008/AuditingImplantableMedicalDevices_ASynergisticApproachforBottom-LineResultsbyDanielEEllisAndChristyDecker.pdf

(1) In general. Subject to paragraph (2), any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

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(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $ 5,000 and not more than $ 10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

The Act goes on to define "knowingly" as:

(b) Definitions. For purposes of this section--

(1) the terms "knowing" and "knowingly"--

(A) mean that a person, with respect to information--

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

31 USC § 3729

## FEDERAL PROGRAMS AFFECTED BY FALSE CLAIMS AT ISSUE HERE

### The Medicare Program

38. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services for elderly and disabled Americans. Part A of the Medicare Program authorizes payment for institutional care, including hospital, skilled nursing facility and home health care. See 42 U.S.C. §§ 1395c-1395i-4. Most hospitals, including those listed as co-conspirators in this complaint, derive a substantial portion of their revenue from the Medicare Program.

39. Part B provides for payment of physician services.

40. HHS is responsible for the administration and supervision of the Medicare Program. CMS, an agency of HHS, is directly responsible for the administration of the Medicare Program.

41. Under the Medicare Program, CMS makes payments retrospectively (after the services are rendered) to providers who provide inpatient cardiology services to Medicare beneficiaries.

42. The services at issue here are stent placements.

43. To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries." 42 U.S.C. §1395h. Fiscal intermediaries, typically insurance companies, are responsible for processing and paying claims and auditing cost reports.

44. Providers submit patient-specific claims for payments electronically on a CMS Form UB-92 (formerly called a HCFA Form UB-92).

**The Medicaid Program**

45. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal government provides matching funds and ensures that states comply with minimum standards in the administration of the program.

46. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation ("FPF"), 42 U.S.C. §§ 1396, *et seq.*

47. Each state's Medicaid program must cover certain outpatient services. 42 U.S.C. §1396a(10)(A), 42 U.S.C. § 1396d(a)(1)-(2).

**The Antikickback Statute**

48. The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. §1320a-7b (the "Antikickback Statute"), provides

for criminal penalties for certain acts impacting Medicare and state health care (e.g., Medicaid) reimbursable services.

49. Section 1320a-7b(b) provides:

> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe or rebate (directly or indirectly, overtly or covertly, in cash or in kind –
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under [Medicare] or a State health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under [Medicare] or a State health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Furthermore, this subsection provides:

(2) whoever knowingly and willfully offers and pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under [Medicare] or a State health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under [Medicare] or a State health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

50. The Antikickback Statute prohibits certain solicitations or receipt of remuneration and the offer or payment of certain remuneration.

51. Section 1320a-7b(b)(2) has generally been applied to broker-style arrangements, whereby an individual offers remuneration to another

individual for the purpose of recommending or referring an individual for the furnishing or arranging for an item or service.

52. In an Antikickback Statute analysis, it is immaterial whether remuneration induces one in a position to refer or recommend. It is sufficient that the remuneration may induce one to refer or recommend. ***United States v. Greber,*** 760 F.2d 68, 71 (3rd Cir.), cert. denied, 474 U.S. 988 (1985).

53. Under ***Greber***, it is also irrelevant that there are other legitimate reasons for the remuneration. If one purpose is to induce the purchase of items reimbursed under Medicare, then the Antikickback Statute is violated. ***Id***. at 71.

**INTRODUCTION TO TRICARE/CHAMPUS**

54. At all times relevant to this Complaint, the Defendant knew that the hospitals they were selling their products to were enrolled in, and sought reimbursement from TRICARE/CHAMPUS.

55. TRICARE/CHAMPUS is a federally-funded program that provides medical benefits, including hospital services, to the spouses and unmarried children of active duty retired service members, to the spouses and unmarried children of reservists who were ordered to active duty for thirty days or longer, and to the unmarried spouses and

children of deceased service members and to retirees. Hospital services at non-military facilities are sometimes provided for active duty members of the armed forces, as well. 10 U.S.C. §§ 1071-1109; 32 C.F.R. § 199 *et seq*.

56. TRICARE/CHAMPUS reimburses cardiology services, including stent placements.

57. In addition, a provider is required to be familiar with its duties and responsibilities under the TRICARE/CHAMPUS program. 32 C.F.R. §§ 199.6(a), 199.9(a)(4).

58. TRICARE/CHAMPUS relies upon the honesty of the provider in disclosing any and all false statements, submissions, errors and necessary corrections or adjustments to charges so that similar adjustments can be made by TRICARE/CHAMPUS.

59. The Defendant, by providing kickbacks to the hospitals at issue, caused those hospitals to submit Requests for Reimbursement to TRICARE/CHAMPUS that were based on their representations that they were in compliance with Medicare and Tricare regulations and were not in violation of the Anti-Markup or Anti-Kickback Statutes.

60. Whenever the Defendant' Requests for Reimbursement were false due to falsity in their representations, employees falsely certified that the

information contained in their Requests for Reimbursement was accurate.

61. Upon information and belief, Defendant knowingly failed to notify TRICARE/CHAMPUS of the no cross kickback scheme and the other violations set forth in this complaint.

62. When the Defendant did not notify TRICARE/CHAMPUS of kickbacks, they permitted the hospitals to accept and retain reimbursement from TRICARE/CHAMPUS of more than they were entitled to receive and retain.

63. The Defendant knew that false claims contained in their violations of the Anti-Kickback Statute would affect TRICARE/CHAMPUS reimbursement as well.

**COUNT I – FALSE CLAIMS RELATING TO ANTIKICKBACK STATUTE**
**(False Claims 31 USC § 3729(a)(1))**
**Defendant Boston Scientific, Inc.**

64. Relator restates, repleads and incorporates by reference paragraphs 1-63 as if fully set forth herein.

65. With respect to the allegations set forth in this count defendant acted with knowledge or knowingly inasmuch as it was actually aware that its conduct was prohibited by the Anti-Kickback Statute; or it, either acted with actual knowledge, acted with deliberate ignorance; or acted

with reckless disregard with respect to these regulations as set forth herein.

66. Defendant Boston Scientific, Inc., caused to be presented to the Fiscal Intermediaries of the United States government, claims for stent placements.

67. The claims presented were false or fraudulent in that:

a. Defendant Boston Scientific, Inc., knew, or in the exercise of reasonable diligence in supervising its sales representatives would have known that the hospitals were receiving free stents in exchange for doing business with Boston Scientific, and that such conduct violated the Anti-Kickback Statute.

b. Defendant Boston Scientific, Inc., knew that not requiring any paper trail on "no cross" stents was subject to abuse but continued and encouraged the process.

c. 42 USC § 1320(a)(7)(b) provides that a "claim that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. A person need not have actual knowledge of the Anti-Kickback Statute nor specific intent to commit an Anti-Kickback Statute violation."

68. Boston Scientific, Inc. caused to be presented, at a minimum, the following false claims:

a. All stent procedures using Boston Scientific stents at St. Mary's Hospital in Jefferson City, Missouri from 2006 to 2010.

b. All stent procedures using Boston Scientific stents at Boone Hospital Center in Columbia, Missouri, from 2006 to 2007.

c. All stent procedures using Boston Scientific stents at Lake Regional Hospital, Freeman Hospital, Cox Hospital, St. John's Mercy Hopsital in Springfield, St. John's Hospital in Joplin, and at any other facility performing PCI serviced by Dave Raridon in Southwest Missouri, from 2006 to 2010.

d. All stent procedures in the St. Louis area in hospitals using Boston Scientific stents.

69. On information and belief, and based on representations made by other Boston Scientific employees, the same type of kickbacks and under-the-table dealings are commonplace at other hospitals throughout the United States and serviced by Boston Scientific, Inc. By looking at the winners of sales competitions run by Boston Scientific, the markets engaging in this conduct will be clear.

70. The payment of kickbacks were material by statute, and also in that they had a natural tendency to influence payment by the government,

or there were capable of influencing the payment of money by the government.

71. As a result of the violations of the Anti-Kickback Statute, the Government of the United States has been damaged in an amount to be proved at trial.

72. Defendant, on information and belief, has been responsible for hospitals submitting in excess of 10,000 false claims a year from 2006 through the present, with the exact number of false claims to be proved at trial.

WHEREFORE, Relator prays for judgment against defendant in the amount of three times the actual damages sustained by the government, for a civil penalty between $5,500 and $11,000 for each separate false claim submitted, for a relator's share of between 15% and 25% of the amount recovered by the government, for his reasonable attorney's fees, expenses and costs of this action. Relator also prays for a relator's share of any alternative remedy elected by the Government, and for such other and further relief as the court deems just.

**COUNT II – FALSE CLAIMS RELATING TO ANTIKICKBACK STATUTE**
**(False Records 31 USC § 3729(a)(2))**
**Defendant Boston Scientific, Inc.**

73. Relator restates, repleads and incorporates by reference paragraphs 1-72 as if fully set forth herein.

74. With respect to the allegations set forth in this count defendant acted with knowledge or knowingly inasmuchas it was actually aware that its conduct in creating false records was wrongful; or it acted with actual deliberate ignorance; or acted with reckless disregard with respect to the creation of these false records as set forth herein.

75. Defendant Boston Scientific, Inc., made and used false records, or caused to be made and used false records that were material to a false or fraudulent claim.

76. The records created were false or fraudulent in that:

a. Defendant's contracts for sale or memoranda of understanding rarely made reference to free stents that would be provided to hospitals.

b. Defendant's invoices did not show credits or other indicia of the kickbacks.

c. Hospitals did not track stents received that they did not pay for.

d. Defendant's agents acted with hospital purchasing managers to allow these agents to pick up stents from hospitals and take them to the agent's house for use in inducing sales at other institutions.

e. 42 USC § 1320(a)(7)(b) provides that a "claim that includes items or services resulting from a violation of the Anti-Kickback Statute

constitutes a false or fraudulent claim for purposes of the False Claims Act. A person need not have actual knowledge of the Anti-Kickback Statute nor specific intent to commit an Anti-Kickback Statute violation."

77. Boston Scientific, Inc. presented, at a minimum, the following false claims and the records and claims forms generated in order to get these claims paid were the false records at issue in this litigation:

a. All stent procedures using Boston Scientific stents at St. Mary's Hospital in Jefferson City, Missouri from 2006 to 2010.

b. All stent procedures using Boston Scientific stents at Boone Hospital Center in Columbia, Missouri, from 2006 to 2007.

c. All stent procedures using Boston Scientific stents at Lake Regional Hospital, Freeman Hospital, Cox Hospital, St. John's Mercy Hopsital in Springfield, St. John's Hospital in Joplin, and at any other facility performing PCI serviced by Dave Raridon in Southwest Missouri, from 2006 to 2010.

d. All stent procedures in the St. Louis area at hospitals using Boston Scientific stents.

78. The false statements and false records made by the defendant were material in that they had a had a natural tendency to influence payment

by the government, or there were capable of influencing the payment of money by the government.

79. As a result of the material false records made by Boston Scientific, Inc., the Government of the United States has been damaged in an amount to be proved at trial.

80. Defendant, on information and belief, has submitted in excess of 10,000 false claims a year from 2006 through the present, with the exact number of false claims to be proved at trial.

WHEREFORE, Relator prays for judgment against defendant in the amount of three times the actual damages sustained by the government, for a civil penalty between $5,500 and $11,000 for each separate false claim submitted, for a relator's share of between 15% and 25% of the amount recovered by the government, for his reasonable attorney's fees, expenses and costs of this action. Relator also prays for a relator's share of any alternative remedy elected by the Government, and for such other and further relief as the court deems just.

**COUNT III – CONSPIRACY TO VIOLATE THE FALSE CLAIMS ACT**
**(31 USC § 3729(a)(1)C)**
**(Defendant Boston Scientific Inc.)**

81. Relator restates, repleads and incorporates by reference paragraphs 1-80 as if fully set forth herein.

82. The following individuals and corporate entities formed the conspiracy pleaded in this Count:

a. Boston Scientific, through its agent Dave Raridon, his managers, supervisors and through its corporate officers.

b. St. Mary's Hospital, Inc., and SSM Healthcare, through its agent in charge of purchasing at St. Mary's Hospital

c. Boone Hospital Center, through its agent in charge of purchasing.

d. Freeman Hospital, through its agent in charge of purchasing.

e. St. John's Mercy Hospital in Joplin, through its agent in charge of purchasing.

f. Lake Regional Hospital, through its agent in charge of purchasing.

g. Cox Hospital, through its agent in charge of purchasing.

h. All other hospitals where Dave Raridon did deals on behalf of Boston Scientific, including certain St. Louis hospitals whose identities are not known but will be discovered.

83. The parties agreed on the following conspiracies to defraud the government:

a. The parties conspired to create false records regarding shipments of stents to the hospitals in order to permit the Boston Scientific agent to use these stents as inducements.

b. The parties conspired to create false records that did not show that the facilities were receiving kickbacks in the form of free goods.

84. Defendant and the co-conspirators committed the following overt acts in furtherance of the conspiracy:

a. Defendant Raridon called in no cross stents to benefit the hospitals.

b. Boston Scientific sent stents to the hospitals to compensate them for the "no cross" stents without any evidence that any stents had failed to cross.

c. Hospitals received stents but did not take them into inventory or otherwise process them so that they would never show up on their books.

85. All conspirators knew the essential purpose or object of the conspiracy was to generate larger billings to Medicare so that they could all share in the proceeds of the conspiracy.

86. In joining the conspiracy defendant, and each of them, acted with the intent to defraud Medicare, Medicaid, Tricare and the Federal Employees Health Insurance Program.

87. As a result of the conspiracy among and between the co-conspirators and the defendant in this action Medicare and the Treasury were damaged in an amount to be proved at trial.

88. Defendant on information and belief, have submitted in excess of 10,000 false claims a year from 2006 through the present, with the exact number of false claims to be proved at trial.

WHEREFORE, Relator prays for judgment against defendant in the amount of three times the actual damages sustained by the government, for a civil penalty between $5,500 and $11,000 for each separate false claim submitted, for a relator's share of between 15% and 25% of the amount recovered by the government, for his reasonable attorney's fees, expenses and costs of this action. Relator also prays for a relator's share of any alternative remedy elected by the Government, and for such other and further relief as the court deems just.

**COUNT IV – REVERSE FALSE CLAIMS**
**Boston Scientific, Inc.,**
**(31 USC § 3729(a)(7)**

89. Relator restates, repleads and incorporates by reference paragraphs 1-88 as if fully set forth herein.

90. Payments were made to the hospitals by the United States through CMS and its fiscal intermediaries for stents placed in the hospitals where kickbacks had been paid in violation of the Anti Kickback Statute and the False Claims Act.

91. Boston Scientific knew that kickbacks had been paid and claims for reimbursement had been tainted because Relator told them so.

92. The hospitals were, on information and belief, aware that they had received inducements to purchase stents that would be used on federal health care beneficiaries in violation of the Anti-Kickback Statute.

93. The United States through CMS and its fiscal intermediaries paid for stents placed while the hospitals were not in compliance with the Anti-Kickback Statute and Boston Scientific was aware that these overpayments created an obligation under the False Claims Act.

94. The defendant acted with knowledge inasmuch as it was either actually aware of the requirements to repay Medicare and Tricare, or acted in deliberate ignorance or reckless disregard of the obligations to repay Medicare and Tricare.

95. Defendant knowingly and improperly avoided an obligation to repay Medicare and Tricare obligations created under the Anti-Kickback statute.

96. Defendant knowingly concealed its obligations to repay Medicare by instructing employees not to report the overpayments to Medicare and by taking steps to silence Jenne, an internal whistleblower.

97. As a result of the conspiracy among and between the co-conspirators and the defendant in this action, Medicare and the Treasury were damaged in an amount to be proved at trial.

98. Defendant on information and belief, have submitted in excess of 10,000 false claims a year from 2006 through the present, with the exact number of false claims to be proved at trial.

WHEREFORE, Relator prays for judgment against defendant in the amount of three times the actual damages sustained by the government, for a civil penalty between $5,500 and $11,000 for each separate false claim submitted, for a relator's share of between 15% and 25% of the amount recovered by the government, for his reasonable attorney's fees, expenses and costs of this action. Relator also prays for a relator's share of any alternative remedy elected by the Government, and for such other and further relief as the court deems just.

Respectfully submitted,

/s/ Anthony L. DeWitt
Edward D. Robertson, Jr. MO # 27183
Mary D. Winter MO #38328
Anthony L. DeWitt MO #41612
Bartimus, Frickleton, Robertson & Gorny, P.C.
715 Swifts Highway
Jefferson City, Missouri 65109
Telephone No.: (573) 659-4454
Facsimile No.: (573) 659-4460

Marsha Fischer, MBE # 45680
700 Cherry St.
Columbia, MO
573-442-2454
573-874-3332 (Fax)
marsha@wasf-law.com

ATTORNEYS FOR RELATOR

**JURY DEMAND**

Relator demands a jury trial on all issues that may be tried to a jury.

/s/ Anthony L. DeWitt
Edward D. Robertson, Jr. MO # 27183
Mary D. Winter MO #38328
Anthony L. DeWitt MO #41612
Bartimus, Frickleton, Robertson & Gorny, P.C.
715 Swifts Highway
Jefferson City, Missouri 65109
Telephone No.: (573) 659-4454
Facsimile No.: (573) 659-4460

**CERTIFICATE OF SERVICE**

Relator certifies that on October 14, 2011, a true and correct copy of the foregoing pleading was served by certified mail, pursuant to Rule 4, on the United States of America, by placing the Complaint and the Evidentiary Disclosure in the United States mail, first class postage prepaid, and addressed to:

Hon. Eric Holder, Esq.
Tony West, Esq.
Joyce R. Branda, Esq.
Commercial Litigation Branch (Frauds)
P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044

Mary Elizabeth Phillips, Esq.
Lucinda Woolery, Esq.
United States Courthouse
Room 5510
400 East 9th Street
Kansas City, MO 64106

/s/ Anthony L. DeWitt
Relators Counsel